JUN 28 2011

Section III 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date of Submission	Jun 8th, 2010
Sponsor	Establishment Registration No.: 3006979678 Contec Medical Systems Co., Ltd, No. 24, West Huanghe Road,Qinhuangdao, Hebei, 066000, China Contact Person: XueYong Li, Quality Manager
Correspondent	Ms. Diana Hong / Mr. Tarzan. Wang Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No.19, Lane 999, Zhongshan Road (S-2), Shanghai, 200030, China T: +86-21-64684973; F: 240-238-7587 Tarzan.wang@mid-link.net
Proposed Device	Patient Monitors, CMS8000
Common Name	Patient Monitor
Classification	Monitor, Physiological, Patient , MHX , 21 CFR 870.1025
Panel	Cardiovascular
Subsequent Code	DSI, MLD, DRT, DXN, DSK, DQA, BZQ, CCK, FLL
Device Description	The proposed device, CMS8000 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters. It has the physical and technical alarming function with audio and visual alarming, The device can driven by AC or DC power supply.
Technological Characteristics	The proposed device, CMS8000 Patient Monitor has no any new technological characteristics, all function and technological characteristic are same or similar as the predicate device.
Intended Use	The CMS8000 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient. The Pulse Oxygen Saturation (SpO2) and Pulse Rate (PR) are intended use for adult and pediatric

	patient. The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance..
Testing	Performance testing including clinical and bench testing was conducted to validate and verify that the proposed device, the Patient Monitors met all design specifications.
Clinical Discussion	The proposed device, General Patient Monitors, has conducted clinical test into performance verification of SpO2 and NIBP measure function according with the standard of ISO 9919 and AAMI SP10.
Non Clinical Discussion	The proposed device, General Patient Monitors, has conducted the test according with the following standard to demonstrate the effectiveness and safety performance of device. IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. AAMI / ANSI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms. ISO 9919:2005: Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. AAMI SP10:2002, Manual, electronic or automated sphygmomanometers. IEC 60601-2-34:2000, Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment. ISO 21647:2004, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors.
SE Conclusion	The proposed device, General Patient Monitors, is Substantially Equivalent (SE) to the Predicate Device, PM-7000 Patient Monitor, K072346

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Contect Medical System Co., Ltd.
c/o Diana Hong
Suite 8D , Zhongxin Zhongshan
Mansion, NO. 19, Lane 999,
Zhong Shan, Shanghai
China 200030

JUN 28 2011

Re: K101692
Trade/Device Name: CMS8000 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection and alarms)
Regulatory Class: Class II (two)
Product Code: MHX, DSI, MLD, DRT, DXN, DSK, DQA, BZQ, CCK, FLL
Dated: June 14, 2011
Received: June 15, 2011

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

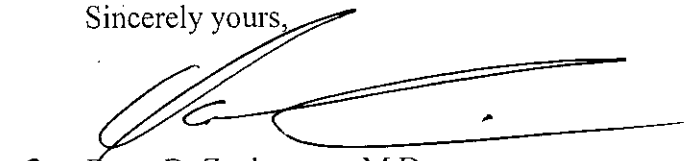
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101692

Section II Indication for Use Statement

510(k) Number:
Device Name: Patient Monitor
Model: CMS8000

Indications for Use:

The CMS8000 Patient Monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.

The Pulse Oxygen Saturation (SpO2) and Pulse Rate (PR) are intended use for adult and pediatric patient.

The monitor is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101692